



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

SEP 29 2004

Mr. Zou Jianhua
President
Yu Shen Tang Chinese Herbal Medicine, LLC
8855 E. Valley Boulevard, #B1
Rosemead, California 91770

Dear Mr. Jianhua:

This is in response to your letter of September 6, 2004 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Yu Shen Tang Chinese Herbal Medicine, LLC is making the following claim for the product Jie Du Ling Capsules:

“Dietary Supplement in assisting the relief of addiction to addictive drugs.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease, namely drug addictions. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

975-0163

LET 784

Page 2 - Mr. Zou Jianhua

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to be 'SJW', with a long horizontal line extending to the right.

Susan J. Walker, M.D.

Director

Division of Dietary Supplement Programs

Office of Nutritional Products, Labeling
and Dietary Supplements

Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

YU SHEN TANG CHINESE HERBAL MEDICINE, LLC.

8855 E Valley Blvd, #B1, Rosemead, CA 91770 Tel: 626-286-0171 Fax: 626-286-0172

Office of Special Nutritionals (HFX-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

SEP 8 11 2004

September 6, 2004

Notification Letter for Statement on Dietary Supplement

Dear FDA officers

I am the president of Yu Shen Tang Chinese Herbal Medicine, LLC, who is, among other things, a manufacturer and distributor of dietary supplements in California. I am writing as per Code of Federal Regulations, Volume 21, Part 101.93, to notify you that we have included statements on the label and in the labeling of one of our products. The following are the information required in this notification letter:

1 Statement of Purpose:

This is a letter to provide notification of a statement of nutritional support, including the exact wording that appears on the label and labeling for a dietary supplement.

2 Vendor Information:

Name, address, telephone and fax numbers of the manufacturer and distributor for mailing and other communication purposes, are as follows:

YU SHEN TANG CHINESE HERBAL MEDICINE, LLC
8855 E. Valley Blvd #B1
Rosemead, CA 91770
Tel: 626-286-0171
Fax: 626-286-0172

3 Product Identification:

The trade name of the product:

89599
100

Jie Du Ling Capsules

The common and usual name of the product:

Jie Du Ling

A label copy showing all information displayed and provided to consumers is attached

4 The text of the Structure/Function Statement:

Dietary Supplement in assisting the relief of addiction to addictive drugs*.

5. Ingredient Statement

This product is a proprietary blend of herbal and other natural ingredients. The following is a complete list of dietary ingredients:

The ingredients are listed in the order of Common Name, Scientific Name in Brackets, Part used, Traditional Chinese Medicine Name in phonetic alphabet.

Tuckahoe (*Poria cocos*) scler of fungus (Fu Lin)
Apricot (*Prunus mandshurica*) seed (Xin Ren)
Eucommia (*Eucommia ulmoides*) bark (Chuan Du Zhong)
Chinese Caterpillar (*Cordyceps senesis*) fungus (Dong Chong Cao)
Thinleaf Milkwort (*Polygala tenuifolia*) root (Yuan Zhi)
Scythian Lamb (*Cibotium barometz*) rhizome (Gou Ji)
Licorice (*Glycyrrhiza uralensis*) root (Gan Cao)
Oyster (*Ostrea gigas*) shell (Mu Li)
Inula (*Inula britannica*) flower (Xuan Fu Hua)
Turmeric (*Curcuma zedoara*) root (Yu Jin)
Chinese Angelica (*Angelica senensis*) root (Dang Gui)
Tangerine (*Citrus reticulata*) peel (Chen Pi)
Wolfberry (*Lycium barbarum*) fruit (Gou Qi Zi)
Polygala (*Polygala telephioides*) entire plate (Jin Niu Cao)
Cyathula (*Cyathula officinalis*) root (Chuan Niu Xi)
Ginseng (*Panax Ginseng*) root (Ren Shen)
Chinese Cassia Tree (*Cinnamomum cassia*) bark (Rou Gui)
Dogwood (*Comus officinalis*) fruit (Shan Zhu Yu)
Gecko (*Gekko gekko*) body (Ge Jie)
Himalayan Teasel (*Dipsacus japonicus*) root (Xu Duan)
Astragalus (*Astragalus membranaceus*) root (Huang Qi)

6. Suggested use: Four capsules (2 g) per dose, twice daily.

Caution: If taking prescription medication, consult your health professionals before use. Store at a dry place below 86° F (30° C), Keep this product and all drugs out of reach of children.

7. Statement of Affirmation:

We, as manufacture and distributor of the above mentioned product, affirm that we have substantiation that the structure/function statement (as shown in No. 4 above) made under 403(6)(r) of the federal Food, Drug and Cosmetic Act is truthful, not misleading, and scientifically valid and that the product does not present a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in the label or labeling.

8 Disclaimer:

At the end of each structure/function statement, there is an asterisk that refers to another asterisk placed adjacent to the disclaimer. The disclaimer is placed at the bottom of the same panel or, in adjacent with the structure/function statement. The disclaimer reads

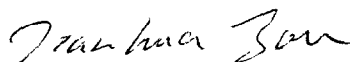
These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Should there be any question or comment, please contact the Vendor through the information in No. 2 above, or contact the preparer of this notification letter:

Geōrge Su
Crosslinks International, Inc.
1800 Century Park East, Suite 600
Los Angeles, CA 90067

Tel: (310)229-5748
Fax: (310)388-1067
E-mail: crosslinks2000@aol.com

Sincerely,



Zou Jianhua
President

Enclosures

Information on Label

Jie Du Ling Capsules

Dietary Supplement in assisting the relief of addiction to addictive drugs*

Net Content: 500 mg x 60 capsules

This product is intended to be used for persons over the age of 18

Suggested Use: Four capsules (2 g) per dose, twice daily.

Do not use if imprinted seal is broken or missing.

Caution: If taking prescription medication, consult your health professionals before use. Store at a dry place below 86° F (30° C), Keep this product and all drugs out of reach of children.

Expiration Date:

**Manufactured by:
Yu Shen Tang Chinese Herbal Medicine, LLC
8855 E. Valley Blvd. #B1, Rosemead, CA 91770**

Product of the USA

*** This statement has not been evaluated by Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.**

Supplement Facts

Serving Size 4 capsules (2 g)

Servings per box 15

Amount per Serving	% Daily Value*
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Calories, Total 5

Total Carbohydrate 0 g	0%
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Proprietary Blend (2 g)

Spiny Date (<i>Ziziphus jujuba</i>) seed (Suan Zao Ren)	†
Tuckahoe (<i>Poria cocos</i>) scler. of fungus (Fu Lin)	†
Apricot (<i>Prunus mandshurica</i>) seed (Xin Ren)	†
Eucommia (<i>Eucommia ulmoides</i>)	
bark (Chuan Du Zhong)	†
Chinese Caterpillar (<i>Cordyceps sinensis</i>)	
fungus (Dong Chong Cao)	†
Thinleaf Milkwort (<i>Polygala tenuifolia</i>) root (Yuan Zhi)	†
Scythian Lamb (<i>Cibotium barometz</i>) rhizome (Gou Ji)	†
Licorice (<i>Glycyrrhiza uralensis</i>) root (Gan Cao)	†
Oyster (<i>Ostrea gigas</i>) shell (Mu Li)	†
Inula (<i>Inula britannica</i>) flower (Xuan Fu Hua)	†
Turmeric (<i>Curcuma zedoaria</i>) root (Yu Jin)	†
Chinese Angelica (<i>Angelica sinensis</i>) root (Dang Gui)	†
Tangerine (<i>Citrus reticulata</i>) peel (Chen Pi)	†
Wolfberry (<i>Lycium barbarum</i>) fruit (Gou Qi Zi)	†
Polygala (<i>Polygala telephoides</i>)	
entire plant (Jin Niu Cao)	†
Cyathula (<i>Cyathula officinalis</i>) root (Chuan Niu Xi)	†
Ginseng (<i>Panax ginseng</i>) root (Ren Shen)	†
Chinese Cassia Tree (<i>Cinnamomum cassia</i>)	
bark (Rou Gui)	†
Dogwood (<i>Comus officinalis</i>) fruit (Shan Zhu Yu)	†
Gecko (<i>Gekko gekko</i>) body (Ge Jie)	†
Himalayan Teasel (<i>Dipsacus japonicus</i>)	
root (Xu Duan)	†
Astragalus (<i>Astragalus membranaceus</i>)	
root (Huang Qi)	†

*Percent Daily Values are based on a 2,000 calorie diet

† Daily Value not established

Label No.: 1081905

Client No.: C07

Product: Jie Du Ling Capsules (60 x 500 mg)